(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 502(b) of the act, shall apply if such insufficiency is caused by:

(1) The use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(2) The use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 502(c) of the act; or

(3) The use of label space for any representation in a foreign language.

(c)(1) All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language: *Provided, however*, That in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language.

§ 801.16 Medical devices; Spanish-language version of certain required statements.

If devices restricted to prescription use only are labeled solely in Spanish for distribution in the Commonwealth of Puerto Rico where Spanish is the predominant language, such labeling is authorized under § 801.15(c).

§ 801.18 Format of dates provided on a medical device label.

(a) *In general.* Whenever the label of a medical device includes a printed expiration date, date of manufacture, or any other date intended to be brought to the attention of the user of the device, the date must be presented in the following format: The year, using four digits; followed by the month, using two digits; followed by the day, using two digits; each separated by hyphens. For example, January 2, 2014, must be presented as 2014–01–02.

(b) *Exceptions.* (1) A combination product that properly bears a National Drug Code (NDC) number is not subject to the requirements of paragraph (a) of this section.

(2) If the device is an electronic product to which a standard is applicable under subchapter J of this chapter, Radiological Health, the date of manufacture shall be presented as required by § 1010.3(a)(2)(ii) of this chapter.

[78 FR 58818, Sept. 24, 2013]

Subpart B—Labeling Requirements for Unique Device Identification

§ 801.20 Label to bear a unique device identifier.

(a) *In general.* (1) The label of every medical device shall bear a unique device identifier (UDI) that meets the requirements of this subpart and part 830 of this chapter.

(2) Every device package shall bear a UDI that meets the requirements of this subpart and part 830 of this chapter.

(b) *Exceptions.* Exceptions to the general rule of paragraph (a) of this section are provided by §§ 801.30, 801.45, and 801.128(f)(2), and § 801.55 provides a means to request an exception or alternative not provided by those provisions.

[78 FR 58818, Sept. 24, 2013]

§ 801.30 General exceptions from the requirement for the label of a device to bear a unique device identifier.

(a) *In general.* The following types of devices are excepted from the requirement of § 801.20; a device within one or more of the following exceptions is not